



FTW

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Hateboer et al.

Serial No.: 10/790,562

Filed: March 1, 2004

For: RECOMBINANT PROTEIN
PRODUCTION IN A HUMAN CELL

Confirmation No.: 9903

Examiner: To be assigned

Group Art Unit: 1653

Attorney Docket No.: 2578-4038.3US

CERTIFICATE OF MAILING

I hereby certify that this correspondence along with any attachments referred to or identified as being attached or enclosed is being deposited with the United States Postal Service as First Class Mail on the date of deposit shown below with sufficient postage and in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

May 24, 2005
Date

Aubry Blackburn
Signature

Aubry Blackburn
Name (Type/Print)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08 be considered by the Examiner and made of record. Copies of U.S. patents are not being submitted pursuant to M.P.E.P. 609 III A(2). Copies of foreign patent documents and non-patent literature are enclosed pursuant to 37 C.F.R. § 1.98(a)(2)

Pursuant to 37 C.F.R. § 1.98(d), a copy of any patent, publication or other information listed in the Information Disclosure Statement is not required to be provided if it was previously cited by or submitted to the office in a prior application, provided that the prior

application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. § 120.

Accordingly, no copy of information marked with a pound sign (#) is enclosed because it was previously cited or submitted to the patent office in a prior application which is properly identified above, and is relied upon for an earlier filing date. The references are as follows:

<u>U.S. Patent Documents</u>		
<u>U.S. Patent No.</u>	<u>Publication Date</u>	<u>Patentee</u>
US-4,703,008	10-27-1987	Lin
US- 4,835,260	05-30-1989	Shoemaker
US- 5,047,335	09-10-1991	Paulson et al.
US- 5,441,868	08-15-1995	Lin
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US- 5,494,790	02-27-1996	Sasaki et al.
US- 5,767,078	06-16-1998	Johnson et al.
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US- 5,789,247	08-04-1998	Ballay et al.
US- 5,830,851	11-03-1998	Wrighton et al.
US- 5,835,382	11-10-1998	Wilson et al.
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US- 2003/0087437 A1	05-08-2003	Asada et al.
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Foreign Patent Documents

<u>Document No.</u>	<u>Publication Date</u>	<u>Patentee</u>
#WO 95/05465	02-23-1995	Amgen Inc.
#WO 98/18926	05-07-1998	G.D. Searle & Co.
#WO 98/39411	09-11-1998	Baxter International Inc.
#WO 98/44141	10-08-1998	The University of British Columbia
#WO 99/05268	02-04-1999	Boehringer Mannheim GMBH
#WO 00/61164	10-19-2000	Kenneth S. Warren Laboratories
#WO 00/63403	10-26-2000	Introgene B.V.
#WO 01/38362 A2	05-31-2001	Crucell Holland B.V.
#WO 02/053580	07-11-2002	The Kenneth S. Warren Institute, Inc.
#WO 03/038100 A1	05-08-2003	Crucell Holland B.V.
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#WO 03/048348 A2	06-12-2003	Crucell Holland B.V.
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#WO 2004/003176	01-08-2004	The Kenneth S. Warren Institute, Inc.
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Other Documents

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#NCBI Entrez Nucleotide accession number U38242.

#NCBI Entrez Nucleotide accession number NC_002018.

#NCBI Entrez Nucleotide accession number X02996 J01967 J01968 J01970 J01971 J01972 J01974 J01976 J01977 J01978 J01979 K00515 V00025 V00026 V00027 V00029.

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#FALLAUX et al., "New helper cells and matched early region 1-deleted adenovirus vectors prevent generation of replication-competent adenoviruses," *Human Gene Therapy*, Sept. 1, 1998, Vol. 9, No. 1, pp. 1909-1917. Abstract.

#GRAND et al., "Modulation of the level of expression of cellular genes in adenovirus 12-infected and transformed human cells," *Eur Mol Biol Organ J.* 1986, 5 (6) 1253-1260. Abstract.

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#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/549,463

Filed: September 3, 2002

For: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL, which application is being relied upon for an earlier filing date under 35 U.S.C.

§ 120.

In compliance with the duty to disclose information material to patentability pursuant to 37 C.F.R. § 1.56, Applicants hereby identify the following listed copending applications naming a common inventor(s):

Serial No.: 10/790,562

Attorney Docket No.: 2578-5832US
Serial No.: 10/381,088
Filed: 3/20/2003
Title: ADENOVIRAL VECTORS PROVIDED WITH A TROPISM FOR DENDRITIC CELLS

Attorney Docket No.: 2578-6386US
Serial No.: 10/494,140
Filed: 4/29/2004
Title: METHODS AND MEANS FOR PRODUCING PROTEINS WITH PREDETERMINED POST-TRANSLATIONAL MODIFICATIONS

Attorney Docket No.: 2578-6448US
Serial No.: 10/497,832
Filed: 1/10/2005
Title: PRODUCTION OF VIRUSES, VIRAL ISOLATES AND VACCINES

Attorney Docket No.: 2578-6471US
Serial No.: 10/499,298
Filed: 10/25/2004
Title: EFFICIENT PRODUCTION OF F(AB')₂ FRAGMENTS IN MAMMALIAN CELLS

Attorney Docket No.: 2578-6546US
Serial No.: 10/512,589
Filed: 10/25/2004
Title: MEANS AND METHODS FOR THE PRODUCTION OF ADENOVIRUS VECTORS

Attorney Docket No.: 2578-6567US
Serial No.: 10/512,602
Filed: 10/25/2004
Title: STABLE ADENOVIRAL VECTORS AND METHODS FOR PROPAGATION THEREOF

Attorney Docket No.: 2578-4489.1US
Serial No.: 10/646,449
Filed: 8/22/2003
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE TROPISM FOR DENDRITIC CELLS AND METHODS OF USE

Serial No.: 10/790,562

Attorney Docket No.: 2578-3982.3US
Serial No.: 10/783,510
Filed: 2/20/2004
Title: MEANS AND METHODS FOR FIBROBLAST-LIKE OR
MACROPHAGE-LIKE CELL TRANSDUCTION

Attorney Docket No.: 2578-3833.10US
Serial No.: 10/850,140
Filed: 5/20/2004
Title: PACKAGING SYSTEMS FOR HUMAN RECOMBINANT
ADENOVIRUS TO BE USED IN GENE THERAPY

Attorney Docket No.: 2578-4070.2US
Serial No.: 10/951,102
Filed: 9/27/2004
Title: SEROTYPES OF ADENOVIRUS AND USES THEREOF

Attorney Docket No.: 2578-6737US
Serial No.: 11/012,546
Filed: 12/14/2004
Title: MEANS AND METHODS FOR REGULATING GENE
EXPRESSION

Attorney Docket No.: 2578-4231.1US
Serial No.: 11/018,669
Filed: 12/20/2004
Title: GENE DELIVERY VECTORS PROVIDED WITH A TISSUE
TROPISM FOR SMOOTH MUSCLE CELLS, AND/OR
ENDOTHELIAL CELLS

Attorney Docket No.: 2578-6448.1US
Serial No.: 11/026,518
Filed: 12/30/2004
Title: OVEREXPRESSION OF ENZYMES INVOLVED IN
POST-TRANSLATIONAL PROTEIN MODIFICATIONS IN
HUMAN CELLS

Attorney Docket No.: 2578-5447.1US
Serial No.: 11/039,767
Filed: 1/18/2005
Title: RECOMBINANT PRODUCTION OF MIXTURES OF ANTIBODIES

Serial No.: 10/790,562

Attorney Docket No.: 2578-6828US
Serial No.: 11/070,890
Filed: 3/2/2005
Title: RECOMBINANT PROTEIN PRODUCTION IN PERMANENT
AMNIOCYTIC CELLS THAT COMPRISE NUCLEIC ACID
ENCODING ADENOVIRUS E1A AND E1B PROTEINS

Attorney Docket No.: 2578-5006.2US
Serial No.: 11/083,590
Filed: 3/18/2005
Title: GENE DELIVERY VECTORS WITH CELL TYPE SPECIFICITY
FOR MESENCHYMAL STEM CELLS

Attorney Docket No.: 2578-6964US
Serial No.: 11/102,073
Filed: 4/8/2005
Title: COMPOSITIONS OF ERYTHROPOIETIN ISOFORMS
COMPRISING LEWIS-X STRUCTURES AND HIGH SIALIC ACID
CONTENT

Attorney Docket No.: 2578-6827US
Serial No.: 11/110,517
Filed: 4/20/2005
Title: VACCINES AGAINST WEST NILE VIRUS

This Supplemental Information Disclosure Statement is believed to be filed before the mailing date of a first Office Action on the merits; therefore, no fee is due.

Respectfully submitted,



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Registration No. 33,041
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Date: May 20, 2005
ACT/alb
Enclosures: Form PTO/SB/08
Cited Documents



PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/790,562
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2578-4038.3US

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US- 4,703,008	10-27-1987	Lin	
		US- 4,835,260	05-30-1989	Shoemaker	
		US- 5,047,335	09-10-1991	Paulson et al.	
		US- 5,441,868	08-15-1995	Lin	
		US- 5,457,089	10-10-1995	Fibi et al.	
		US- 5,494,790	02-27-1996	Sasaki et al.	
		US- 5,767,078	06-16-1998	Johnson et al.	
		US- 5,773,569	06-30-1998	Wrighton et al.	
		US- 5,789,247	08-04-1998	Ballay et al.	
		US- 5,830,851	11-03-1998	Wrighton et al.	
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		US- 5,856,298	01-05-1999	Strickland	
		US- 6,033,908	03-01-2000	Bout et al.	
		US- 6,492,169 B1	12-10-2002	Vogels et al.	
		US- 6,558,948	05-06-2003	Kochanek et al.	
		US- 6,855,544	02-15-2005	Hateboer et al.	
		US- 2002/116723 A1	08-22-2002	Grigliatti et al.	
		US- 2003/0087437 A1	05-08-2003	Asada et al.	
		US- 2003/0092160	05-15-2003	Bout et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
		#WO 95/05465	02-23-1995	Amgen Inc.		
		#WO 98/18926	05-07-1998	G.D. Searle & Co.		
		#WO 98/39411	09-11-1998	Baxter International Inc.		
		#WO 98/44141	10-08-1998	The University of British Columbia		
		#WO 99/05268	02-04-1999	Boehringer Mannheim GMBH		
		#WO 00/61164	10-19-2000	Kenneth S. Warren Laboratories		
		#WO 00/63403	10-26-2000	Introgene B.V.		
		#WO 01/38362 A2	05-31-2001	Crucell Holland B.V.		
		#WO 02/053580	07-11-2002	The Kenneth S. Warren Institute, Inc.		
		#WO 03/038100 A1	05-08-2003	Crucell Holland B.V.		
		#WO 03/048197 A1	06-12-2003	Crucell Holland B.V.		
		#WO 03/048348 A2	06-12-2003	Crucell Holland B.V.		
		#WO 03/051927	06-26-2003	Crucell Holland B.V.		
		#WO 2004/003176	01-08-2004	The Kenneth S. Warren Institute, Inc.		
		#WO 2004/099396	11-18-2004	Crucell Holland B.V.		
		#EP 0 411 678	02-06-1991	Genetics Institute, Inc.		

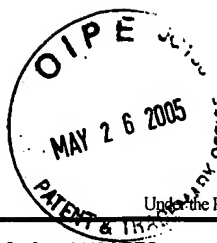
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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 2 of 3

Complete if Known

Application Number	10/790,562
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2578-4038 3LIS

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#GHOSH-CHOUDHURY et al., Protein IX, a minor component of the human adenovirus capsid, is essential for the packaging of the full length genomes, The EMBO Journal, 1987, pp. 1733-39, Vol. 6, No. 6.	
		#LOUIS et al., Cloning and Sequencing of the Cellular--Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line, Virology, 1997, pp. 423-29, Vol. 233.	
		#NCBI Entrez Nucleotide accession number U38242.	
		#NCBI Entrez Nucleotide accession number NC_002018.	
		#NCBI Entrez Nucleotide accession number X02996 J01967 J01968 J01970 J01971 J01972 J01974 J01976 J01977 J01978 J01979 K00515 V00025 V00026 V00027 V00029.	
		#SETOGUCHI et al., "Stimulation of Erythropoiesis by in vivo gene therapy: Physiologic consequences of transfer of the human erythropoietin gene to experimental animals using an adenovirus vector," Blood, November 1, 1994, pp. 2946-53, Vol. 84, No. 9.	
		#European Search Report 05 10 0732, April 7, 2005.	
		#FALLAUX et al., "New helper cells and matched early region 1-deleted adenovirus vectors prevent generation of replication-competent adenoviruses," Human Gene Therapy, Sept. 1, 1998, Vol. 9, No. 1, pp. 1909-1917. Abstract.	
		#GRAND et al., "Modulation of the level of expression of cellular genes in adenovirus 12-infected and transformed human cells," Eur Mol Biol Organ J. 1986, 5 (6) 1253-1260. Abstract.	
		#GRAND et al., "The high levels of p53 present in adenovirus early region 1-transformed human cells do not cause up-regulation of MDM2 expression," Virology, 1995, Vol. 210, No. 2, pp. 323-334. Abstract.	
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		#BOUT et al., "Improved helper cells for RCA-free production of E1-deleted recombinant adenovirus vectors," Cancer Gene Therapy, 1996, pp. S24, Vol. 3, No. 6.	
		#PAU et al., Abstract, The human cell line PER.C6 provides a new manufacturing system for the production of influenza vaccines, Vaccine, Mar. 21, 2001, pp. 2716-21, Vol. 19, No. 17-19.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B(10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3 of 3

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Application Number	10/790,562
Filing Date	March 1, 2004
First Named Inventor	Hateboer et al.
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	2578-4038 3US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		#CARROLL et al., Abstract, Differential Infection of Receptor-modified Host Cells by Receptor-Specific Influenza Viruses, Virus Research, Sep. 1985, pp. 165-79, Vol. 3, No. 2.	
		#SCHIEDNER et al., Abstract, Efficient transformation of primary human amniocytes by E1 functions of Ad5: generation of new cell lines for adenoviral vector production, 2000, Hum. Gene Ther. 11, 2105-2116.	
		#PAZUR et al., Abstract, Oligosaccharides as immunodeterminants of erythropoietin for two sets of anti-carbohydrate antibodies, Journal of Protein Chemistry, November 2000, pp. 631-35, Vol. 19, No. 8.	
		#CRONAN, Abstract, Biotination of Proteins in-vivo a post-translational modification to label purify and study proteins, Journal of Biological Chemistry, June 25, 1990, pp. 10327-33, Vol. 265, No. 18.	
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Examiner Signature		Date Considered	

#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are not being provided since they were previously cited by or submitted to the Office in the following prior application:

Serial No.: 09/549,463

Filed: September 3, 2002

For: RECOMBINANT PROTEIN PRODUCTION IN A HUMAN CELL, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.

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